

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

<p>IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</p>	<p>MDL No. 2875</p>
<p>THIS DOCUMENT RELATES TO ALL CASES</p>	<p>HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)</p>

**CERTIFICATION OF ADAM M. SLATER IN SUPPORT OF
PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE
THE LIABILITY OPINION OF STEPHEN HECHT, PH.D.**

ADAM M. SLATER, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' opposition to Defendants' motion to exclude the liability opinion of Stephen Hecht, Ph.D.
2. Attached hereto as **Exhibit 1** is a true and accurate copy of Dr. Hecht's CV.
3. Attached hereto as **Exhibit 2** is a true and accurate copy of the transcript of Dr. Hecht's August 17, 2021 deposition in this case.
4. Attached hereto as **Exhibit 3** is a true and accurate copy of FDA, *FDA presents interim limits of nitrosamines in currently marketed ARBs* (Dec. 19, 2018).
5. Attached hereto as **Exhibit 4** is a true and accurate copy of EPA, *N-Nitrosodimethylamine*.

6. Attached hereto as **Exhibit 5** is a true and accurate copy of EPA, *N-Nitrosodiethylamine*.

7. Attached hereto as **Exhibit 6** is a true and accurate copy of USP, Summary, Highlights and Timeline of General Chapter <1469> Nitrosamine Impurities (July 20, 2018).

8. Attached hereto as **Exhibit 7** is a true and accurate copy of Jinsheng Lin's July 27, 2017 email, English translation, ZHP00190573.

9. Attached hereto as **Exhibit 8** is a true and accurate copy of the transcript of Min Li's April 20, 2021 deposition in this case.

10. Attached hereto as **Exhibit 9** is a true and accurate copy of PRINSTON00075497.

11. Attached hereto as **Exhibit 10** is a true and accurate copy of *FDA Statement on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues*, p. 2 (Jan. 25, 2019).

12. Attached hereto as **Exhibit 11** is a true and accurate copy of PRINSTON00077339.

13. Attached hereto as **Exhibit 12** is a true and accurate copy of ZHP00662283.

14. Attached hereto as **Exhibit 13** is a true and accurate copy of ZHP's May 13, 2022 stipulation in this case.

15. Attached hereto as **Exhibit 14** is a true and accurate copy of the transcript of Min Li's April 21, 2021 deposition in this case.

16. Attached hereto as **Exhibit 15** is a true and accurate copy of the transcript of Fengtian Xue's deposition in this case.

17. Attached hereto as **Exhibit 16** is a true and accurate copy of the relevant portion of IARC, *Some Nitroso Compounds* (Lyons, Fr. 1978).

18. Attached hereto as **Exhibit 17** is a true and accurate copy of Lee, Shen, & Grinberg, *Identification and Control of Impurities for Drug Substance Development using LC/MS and GC/MS*, J. of Liquid Chromatography & Related Tech. (Aug. 7, 2008).

19. Attached hereto as **Exhibit 18** is a true and accurate copy of ZHP01746278.

20. Attached hereto as **Exhibit 19** is a true and accurate copy of SYNCORES00001458.

21. Attached hereto as **Exhibit 20** is a true and accurate copy of SOLCO00027588.

22. Attached hereto as **Exhibit 21** is a true and accurate copy of ZHP00359798.

23. Attached hereto as **Exhibit 22** is a true and accurate copy of ZHP01390018.

24. Attached hereto as **Exhibit 23** is a true and accurate copy of the transcript of Peng Dong's March 31, 2021 deposition in this case.

25. Attached hereto as **Exhibit 24** is a true and accurate copy of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

26. Attached hereto as **Exhibit 25** is a true and accurate copy of *Player v. Motiva Enterprises LLC*, No. Civ. 02-3216(RBK), 2006 WL 166452 (D.N.J. Jan. 20, 2006).

27. Attached hereto as **Exhibit 26** is a true and accurate copy of *Geiss v. Target Corp.*, No. 09-2208 (RBK/KMW), 2013 WL 4675377 (D.N.J. 2013).

28. Attached hereto as **Exhibit 27** is a true and accurate copy of the transcript of Jun Du's May 28, 2021 deposition in this case.

29. Attached hereto as **Exhibit 28** is a true and accurate copy of Long, G., Meek, M.E. *Concise International Chemical Assessment Document 31: N,N-Dimethylformamide*. at 5 (WHO 2001).

30. Attached hereto as **Exhibit 29** is a true and accurate copy of Dr. Hecht's supplemental list of materials reviewed.

31. Attached hereto as **Exhibit 30** is a true and accurate copy of Juillard, J. *Dimethylformamide: Purification, Tests For Purity And Physical Properties*. Int'l Union of Pure and Applied Chem. Pergamon Press pp. 885-892 (1977).

32. Attached hereto as **Exhibit 31** is a true and accurate copy of Gowenlock, B.G., Hutchinson, R.J., Little, J., Pfab, J. *Nitrosative dealkylation of some symmetrical tertiary amines*. J. Chem. Soc., Perkin Trans. 2, at 1110 (1979).

33. Attached hereto as **Exhibit 32** is a true and accurate copy of Shandong Hualu-Hengsheng Chemical Co., Ltd., COA, Batch No. 20101026.

34. Attached hereto as **Exhibit 33** is a true and accurate copy of Zhejiang Jianye Chemical Co., Ltd, COA, 11/25/12.

35. Attached hereto as **Exhibit 34** is a true and accurate copy of the transcript of Eric Gu's April 5, 2021 deposition in this case.

36. Attached hereto as **Exhibit 35** is a true and accurate copy of Noel et al., *Unveiling the Influence of pH on the Crystallization of Hybrid Perovskites, Delivering Low Voltage Loss Photovoltaics*, Joule 1 (Oct. 11, 2017).

37. Attached hereto as **Exhibit 36** is a true and accurate copy of Magtaan, et al., *Regeneration of aged DMF for use in solid-phase peptide synthesis*, J. Pep Sci. (2019).

38. Attached hereto as **Exhibit 37** is a true and accurate copy of *Westley v. Ecolab, Inc.*, No. Civ.A.03-CV-1372, 2004 WL 1068805 (E.D. Pa. 2004).

39. Attached hereto as **Exhibit 38** is a true and accurate copy of Smith, P.A.S. & Loepky, R.N. *Nitrosative Cleavage of Tertiary Amines*, *J. of the Am. Chem. Soc.* 89 (5), 1147-1157 (1967).

40. Attached hereto as **Exhibit 39** is a true and accurate copy of Fiddler, W., Pensabene, J., Doerr, R. et al. *Formation of N-Nitrosodimethylamine from Naturally Occurring Quaternary Ammonium Compounds and Tertiary Amines*. *Nature* 236, 307 (1972).

41. Attached hereto as **Exhibit 40** is a true and accurate copy of Sun, Z., Liu, Y.D., and Zhong, R.G. *Theoretical investigation of N-nitrosodimethylamine formation from nitrosation of trimethylamine*. *J. Phys. Chem. A.* 114, 455-65 (2010).

42. Attached hereto as **Exhibit 41** is a true and accurate copy of PRINSTON0076100.

43. Attached hereto as **Exhibit 42** is a true and accurate copy of the transcript of Peng Dong's April 1, 2021 deposition in this case.

44. Attached hereto as **Exhibit 43** is a true and accurate copy of the transcript of Peng Dong's April 2, 2021 deposition in this case.

45. Attached hereto as **Exhibit 44** is a true and accurate copy of *In re Front Loading Washing Mach. Class Action Litig.*, Civil Action No. 08-51(FSH), 2013 WL 3466821 (D.N.J. July 10, 2013).

MAZIE SLATER KATZ & FREEMAN, LLC
Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: April 11, 2023